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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

LIEKEL

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/234,733	Applicant(s) Jiang et al
	Examiner LI Lee	Group Art Unit 1645
	[Barcode]	

Responsive to communication(s) filed on Oct 27, 1900

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 1-12 is/are pending in the application.  
 Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 1-12 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a))  
 \*Certified copies not received \_\_\_\_\_  
 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Art Unit: 1645

## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on Oct 27, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/234,733 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-12 are indefinite for using the term "at least about" in the claims. The term "at least about" is a relative term which renders the claims indefinite. The term "at least about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the

Art Unit: 1645

comparison of sequences, one of the ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed subject matter.

Claims 1-12 are indefinite for using the terms "the nucleotide sequence shown at positions 157 through 924" and "the nucleotide sequence shown at positions 241 through 924" in the claims. It is unclear whether applicant intends to indicate the nucleotide sequence has the nucleotide sequence 157 through 924/ 241 through 924 of SEQ ID NO:1 or to indicate the nucleotide sequence has the nucleotide sequence of any positions of 157 through 924/ 241 through 924 of SEQ ID NO:1. In the absence of a clear recitation of the specific sequences, one of the ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed subject matter.

#### ***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-12 are drawn to an isolated nucleic acid molecule with a recited

portion of SEQ ID NO:1 or positions

Art Unit: 1645

The claims encompass any randomly truncated nucleotide molecule with the recited degree of change of SEQ ID NO:1. However, the specification is limited to the nucleic acid sequence SEQ ID NO:1 which encodes the polypeptide of SEQ ID NO:2, a <sup>Y</sup>  
<sup>A</sup> Streptococcus uberis CAMP factor. The specification only states that DNA sequence homology can be determined by hybridization of polynucleotide (page 16). The claimed nucleic acid molecule is not supported by either a specific and substantial asserted utility or a well established utility because the specification fails to assert any utility for the nucleic acid molecule and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed nucleic acid molecule such that any utility would be well established for the nucleic acid molecule.

Claims 1-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

#### *Claim Rejections - 35 USC § 112*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and means of making and using it, in such full, clear, concise, and exact terms as to enable any

Art Unit: 1645

7. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid molecule ~~15~~ SEQ ID NO:1 which encodes the polypeptide of SEQ ID NO:2, does not reasonably provide enablement for any variant of the nucleic acid molecule ~~15~~ SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-12 are drawn to an isolated nucleic acid molecule with a recited degree of change of a polynucleotide sequence at positions 157-924 of SEQ ID NO:1 or positions 241-924 of SEQ ID NO:1, vectors containing the sequence, host cells containing the vectors, and method of producing the recombinant CAMP factor. The claims encompass any randomly truncated nucleotide acid molecule with the recited degree of change of SEQ ID NO:1. The specification fails to provide characteristics of any nucleic acid molecule with a recited degree of change which will encode the polypeptide variants of the SEQ ID NO:2 with the function a Streptococcus uberis CAMP factor. The specification fails to teach what the critical portions of SEQ ID NO:1 are needed for encoding polypeptide variants of SEQ ID NO:2 with activity. Protein chemistry is probably one of the most unpredictable areas of biotechnology and the art teaches that the significance of any particular amino acid and sequences for different aspects of biological activity can not be predicted *a priori* and must be

Art Unit: 1645

of any truncations and variant of SEQ ID NO:1 that encode a protein with functions equivalent to the protein of SEQ ID NO:2, the lack of an enabling description of how to obtain and make and use the truncation and variant of nucleotide acid sequence of SEQ ID NO:1, the unpredictability associated with making and using the truncation and variant of nucleotide acid sequence of SEQ ID NO:1 encompassed in the scope of the claims as set forth above, the skilled artisan would be forced into undue experimentation to practice (i.e. make and use) the invention as is broadly claimed.

8. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

As to claims 1-12 the specification as originally filed fails to provide written support for the nucleotide sequence shown at positions 157-924 of SEQ ID NO:1 and the nucleotide sequence shown at positions 241-924 of SEQ ID NO:1. This issue is best resolved by applicant pointing to the specification by page and line number where the written description support for the now claimed nucleotide sequence shown at positions 157-924 of SEQ ID NO:1 and the nucleotide sequence shown at positions 241-924 of SEQ ID NO:1 can be found.

Art Unit: 1645

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Podbielski (*Med Microbiol Immunol* 183:239-256, 1994).

Claims 1-3 read on an isolated nucleic acid molecule with any length (e.g., a single nucleic acid) having the recited identity to the nucleotide sequence of any position of 157 through 924 or 241 through 924 of SEQ ID NO:1.

Podbielski teaches an isolated nucleic acid molecule encoding group B *Streptococcus* CAMP factor comprising a sequence having 100% identity to various positions of 157 ~~through~~ 924 and 241 ~~through~~ 924 of SEQ ID NO:1 (see the sequence comparison of USPTC ~~Exhibit~~ to paper No. 9). Thus, Podbielski meets the limitations of the claims.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*An invention may not be patented if it is not significantly different from a known invention, having ordinary skill in the art to which said subject matter pertains, and cannot be distinguished in such manner in which the invention was made.*

Art Unit: 1645

11. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Podblielski (Med Microbiol Immunol 183:239-256, 1994) applied to claims 1-3 and Sambrook et al. (Molecular Cloning, A Laboratory Manual CSH 1989, 17 Expression of Cloned Genes in *Escherichia coli*).

Podblielski teaches a cloned nucleic acid molecule encoding group B *Streptococcus* CAMP factor comprising a sequence having 100% identity to various positions of 157 through 924 and 241 through 924 of SEQ ID NO:1.

Podblielski does not teach inserting the cloned gene into an expression vector comprising heterologous control elements that are operably linked <sup>-to</sup> <sub>a</sub> DNA sequence which can be transcribed and translated in a host cell.

However, Sambrook et al. teach a standard method for expression of cloned genes (see pages 17.2-17.44, especially pages 17.3-17.4) including inserting a gene into a recombinant vector comprising heterologous control elements that are operably linked <sup>-to</sup> <sub>a</sub> DNA sequence which can be transcribed and translated in a host cell.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to insert the cloned gene of Podblielski into a recombinant vector comprising heterologous control elements that can be operably linked <sup>-to</sup> <sub>n</sub> the cloned sequence which can be transcribed and translated in a host cell due to the established advantages

Thus, the claimed invention as a whole was clearly predictable.

Art Unit: 1645

*Status of Claims*

12. No claims are allowed. All claims stand rejected.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee  
January 9, 2001

*Lynette R. F. Smith*  
LYNETTE R. F. SMITH  
- MICROFILM EXAMINER